EXHIBIT 2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
CHEN et al.

Application No.: 10/563,078 Group Art Unit: 4173

Filing Date: June 8, 2006 Examiner: Nissa M. Westerberg

For: Matrix Adjuvants And The Drop Pills Prepared With Them

DECLARATION UNDER 37 C.F.R. § 1.132

I Chen Jianming, do hereby declare as follows:

1. My name is Chen Jianming. I received a bachelor's degree in pharmacology from the Second Military Medical University in 1987, an M.S. in pharmacology from ShenYang Pharmaceutical University in 1994 and a Ph.D from ShenYang Pharmaceutical University in 1999. I completed my post doctoral research at the Second Military Medical University in 2001.

2. I began my career at the Second Military Medical University, where I focused on the research and development of new drug formulation and new pharmaceutical technology. I authored numerous articles in scientific journals published in P. R. China and other countries.

3. I am the inventor of the subject matter of the above-identified patent application, application serial no. 10/563,078 (the '078 application).

4. It is my understanding that the claims of the '078 application were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Okada et al. (US 6,455,053) and by DuRoss (US 5,075,291); and under 35 U.S.C. §103(a) as allegedly obvious over Okada et al. and DuRoss.

5. I have read at least the pertinent portions of the Okada et al. reference as it applies to the 102(b) and 103(a) rejections of claims 1-3, 6, 7, 13 and 14 and the DuRoss references as it applies to the 102(b) and 103(a) rejections of claims 1- 3, 13 and 14.

6. It is my opinion that the resulting drop pill as claimed in the '078 application is different from the product of Okada et al. and the product of DuRoss.

7. Comparative tests were conducted comparing the drop pill of the '078 application with the product of Okada et al. so as to determine hardness and disintegration of the respective products. Samples were prepared according to Example 1 of the '078 application and Example 12 of Okada et al. Example 1 of the '078 application provides that pellets of a molten mixture of the pharmaceutical active ingredient and the matrix adjuvant be dropped into a liquid coolant. Example 12 of the Okada et al. provides that a suspension of the pharmaceutical active ingredient and saccharide be charged into a mold and air-dried, following by additional slow drying.

8. Hardness of the products was determined using a 78X-2B four functions tablet tester (Shanghai Huanghai Instrument Co., Ltd.). Disintegration time was performed according to the method described in Chinese Pharmacopoeia (2005, Appendices XA). Oral disintegration time was performed using healthy volunteers. Samples were orally taken by the volunteers one tablet at a time and the disintegration time was recorded.

9. Table 1 below shows that as compared to the product prepared in accordance with Example 12 of Okada et al., the drop pill prepared in accordance with Example 1 of the '078 application has an average hardness that is higher and a significantly longer average disintegration time.

Table 1

Sample	Average hardness (Kgf)	Average disintegration time (seconds)	Average oral disintegration time (seconds)
Drop Pill of '078 application	3.88	93.6	148
Product of Okada et al	2.53	6.5	15.3

10. Moreover, in the preparation process of the '078 application, the moisture is removed during the melting procedure, and no evaporation or sublimation happens during the formation of a drop pill. Thus, no micro-pores are produced in the drop pill prepared in accordance with the process of the '078 application. On the contrary, all methods disclosed by Okada et al. require the removal of moisture or solvent from the mixture. Thus, evaporation happens during the formation of the solid. As one skilled in the art, I expect this to result in a product containing multiple micro-pores. As a result, I expect the preparation disclosed by Okada et al. to produce a product that is loose in structure, contains many micro-pores and has a rough surface. In contrast, the drop pill produced in accordance with the '078 application produces a product that has higher density and a smoother surface.

11. The differences in structure and properties between the drop pill claimed in the '078 application and the product produced in accordance with the method disclosed by Okada et al. are summarized in Table 2.

Table 2

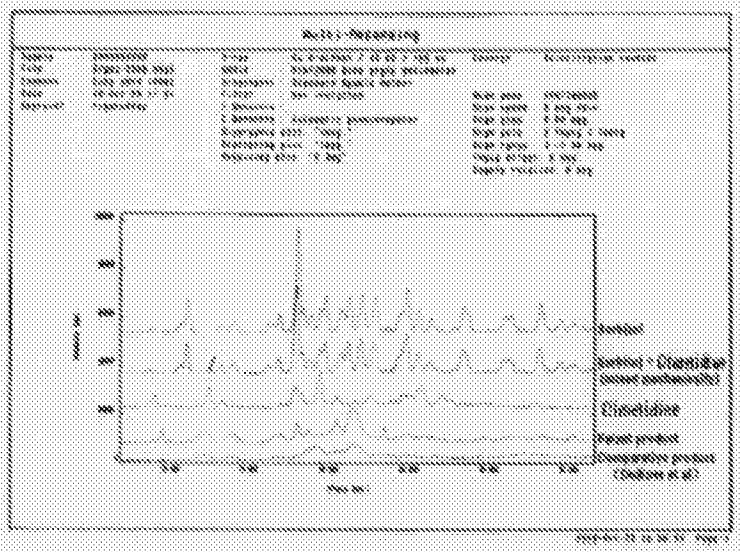
structure and properties	Drop Pill of the '078 application	Product disclosed by Okada et al.
structure	dense	loose
Micro-pores in structure	none	many
surface	smooth	rough
density	high	low
hardness	high	low

12. Comparative tests were conducted comparing the drop pill claimed in the '078 application with the product of DuRoss to determine the crystalline state and the dissolution rate.

13. Example 1 of the '078 application and Example 5 of DuRoss were prepared with cimetidine and sorbitol. Example 1 of the '078 application provides that pellets of a molten mixture of the pharmaceutical active ingredient and the matrix adjuvant be dropped into a liquid coolant. Example 5 of DuRoss discloses placing a melt, consisting of the pharmaceutical active ingredient and a sugar alcohol, on a tray to dry and slowly cooling until crystallized. The crystallized product is then ground to provide a powder that can be make into tablets.

14. The samples were tested using X-ray diffraction analyzer. Figure 1 below shows the X-ray diffraction patterns of the samples and shows that the drop pill claimed in the '078 application has a lower crystalline diffraction peak intensity as compared to the product of DuRoss. This shows that the drop pill claimed in the '078 application has a different crystalline state.

Figure 1



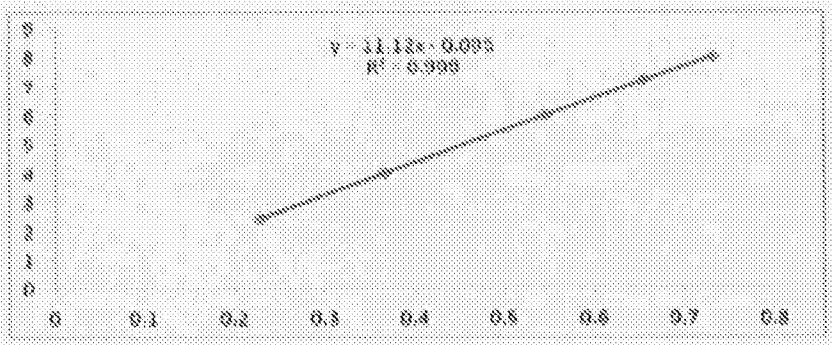
Patent product is the product claimed in the '078 application

Comparative product is the product of the DuRoss reference.

15. Different crystalline states results in different pharmaceutical properties. This was proven by comparing the dissolution rate of the drop pill claimed in the '078 application and the DuRoss product.

16. The maximum absorption wavelength was determined using 10 mg cimetidine dissolved in 10 ml, pH 6.8 PBS. A maximum absorption at 218 nm was observed scanning with a UV-visible spectrophotometer. No absorption was observed for the adjuvant. Five samples of PBS with cimetidine were prepared and tested for UV absorption at 218 nm. Figure 2 shows a curve with the absorbencies as X-axis and the concentration as Y-axis.

Figure 2



17. Dissolution rate was determined according to the methods in Appendix XC of Chinese Pharmacopoeia 2005 Edition, using a dissolution medium of pH 6.8 PBS with a volume of 900 ml. Samples of similar volumes were tested as follows: 10 ml sample was sampled at 2 min, 5 min, 10 min and 20min. The content was calculated from the above-described curve and thus the dissolution percentage was calculated. The data in Table 3 shows the different dissolution rates confirming that the different states of the drop pill claimed in the '078 application and the DuRoss product result in different pharmaceutical properties.

Table 3

Time（minutes）	2 min	5 min	10 min	20 min
Dissolution Percentage of the product of DuRoss	73.55%	98.96%	99.82%	100.00%
Dissolution Percentage of the drop pill of the'078 application	94.60%	99.84%	99.70%	100.00%

18. It is my opinion, based on the above comparative tests, that the drop pill of the '078 application is remarkably different from the product disclosed by Okada et al. and the DuRoss product both in structure and properties. I expect that these differences result in a drop pill that is more resistant to pressure and is easier to transport and store.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under '1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the patent.

Date: January 11, 2010

Chen Jianming

Chen Jianming